REMARKS

Independent claims 1 and 27 have been amended to remove the recently added limitation of the ratio between the topical corticosteroid cream and the antihistamine. Dependent claims 6 and 29 have also been amended to reflect ratios correctly supported by the Specification after a recalculation. New claims 43 and 44 have been added.

In the Office Action dated March 24, 2009, the examiner rejected claims 1-6, 12-20, 26-35 and 41-42 under 35 U.S. C. section 103(a) as being unpatentable over Roberts (US5750141) in view of Platt (WO/9810647 A1) in view of McCadden (US 6479 058), O'Kane et al (The Physician and sportsmedicine Sept. 1999 vol. 27(9) pp. 1-14 and Healthchemist (online pharmacy printout or Naphcon being sold).

According to the examiner, in the combination of references (Roberts and Platt etc.) the primary reference is Roberts. As demonstrated below, based on several reasons Roberts cannot be combined with the other references to teach the claimed invention and is therefore an ineffective reference against the pending claims.

One of the manifestations of the problem that the present invention solves is uncomfortable and unexpected breakouts in dermatological conditions that are bothersome and embarrassing. The Specification (page 1, lines 14-15) gives the example of an actor on the set who whose skin erupts with such a condition and has to leave the set to self-medicate and then wait for the results. The present invention allows one to self-medicate with known formulations (e.g. eye drops)

containing a combination of pheniramine maleate with naphazoline HCL and hydrocortisone) to achieve speedy and dramatic results to relieve skin conditions.

Roberts is an ineffective reference regarding the patentability of the present invention for several reasons. The first reason is that without undue further experimentation, (i) one would not even know from reading Roberts whether Roberts can be applied with Platt to generate relief of the dermatological symptoms that the present invention relieves using the particular compounds that the present invention uses and (ii) if Roberts somehow can be applied with Platt one would not know *how* Roberts can be applied to generate this relief from symptoms without undue further experimentation.

Roberts does not teach how to carry out the steps of his method with respect to the combination of pheniramine maleate and hydrocortisone as the therapeutic agent using naphazoline HCL or phenylephrine HCL as the decongestant/vaso-active agent. Roberts merely teaches (column 11 lines 4-8) that at certain depths of penetration, topical application of phenylephrine at certain concentrations increases the concentration or local perfusion of a particular therapeutic agent i.e. salicylic acid and keeps its concentration at the same level or even decreases it for other levels of concentration of phenylephrine. Roberts further teaches that at other depths of penetration, topical application of phenylephrine may increase or decrease the concentration or local perfusion of salicylic acid depending on the concentration of phenylephrine.

The only discussion in Roberts about having tested either of the

decongestants utilized by the present invention is in Example 1 (column 9 line 40 to column 11 line 40) in which Roberts tested phenylephrine with three therapeutic agents, namely salicylic acid, tritiated water and lidocaine. The results of the experiment differed between the therapeutic agents and showed that the concentration of phenylephrine has to be carefully monitored and controlled because while at one particular concentration used with salicylic acid as the therapeutic agent the decongestant increased the concentration of this therapeutic agent, in underlying tissues, at other not very different concentrations of phenylephrine HCL, the concentration of the same therapeutic agent was kept about the same (and even decreased systemically). Furthermore, the effects varied with the therapeutic agent so the results cannot be expected to apply to the particular therapeutic agent of the claimed invention – if one views the combination of hydrocortisone and pheniramine maleate as the therapeutic agent.

Furthermore, the results depended entirely on the depth of penetration of the therapeutic agent. Since the depth of penetration needed of the antihistamine and corticosteroid used in the method of the present invention is not known and cannot be assumed to be limited to the dermis, it is completely unclear whether the teachings of Roberts can even be successfully utilized in the present invention. It is not at all obvious to combine it with Platt to reach the present invention.

Roberts also teaches nothing about the results of using phenylephrine HCL with the specific therapeutic agent of the present invention (the combination

of pheniramine maleate and hydrocortisone). In fact, just the opposite is the case. Roberts teaches that it is not known what the results would be because Roberts' own method requires one to first try to correlate the concentration of the decongestant with the concentration of the therapeutic agent. Even if one wanted to try using phenylephrine one would have to engage in extensive experimentation to figure out how to do so. The data regarding salicylic shows the increased perfusion/concentration is highly dependent on the concentration of the decongestant. And that is for salicylic acid as the therapeutic agent. Who knows what a graph would look like for the combination of pheniramine maleate and hydrocortisone in relation to phenylephrine HCL. And who knows without further experimentation whether the resulting range of helpful concentrations would even be practical.

Even after reading Roberts, one would still have to carry out extensive and costly experimentation to determine what concentration, if any, of naphazoline HCL or phenylephrine HCL would correlate with what degree of penetration of a therapeutic agent comprising the combination of pheniramine maleate and hydrocortisone relative to what initial concentration of this combination of pheniramine maleate and hydrocortisone. Thus one would have to first determine the depth of penetration necessary to cure the dermatological conditions and one cannot assume relief is wholly based on the dermis layer. Then one would have to see if phenylephrine helps absorption of the therapeutic agent (the combination of pheniramine maleate and hydrocortisone). One would also have to determine what concentration of phenylephrine HCL is appropriate

to increase local perfusion and/or concentration of the combination of pheniramine maleate and hydrocortisone. Finally, one would have to see if the amounts of concentration could be sufficiently monitored and controlled. Finally, after all that were achieved, one would still have to conduct extensive experiments to see if increased concentrations even translated into increased effectiveness. Of course, all of Roberts experiments were on rats whereas Applicant's experiments were on humans patients.

In addition, Roberts does not teach anything about a simple effective treatment that can be administered easily by the average patient or one that can employ existing formulations. In fact, Roberts is highly impractical for such applications. Roberts requires a technologically sophisticated complex procedure out of the capabilities of the average self-medicating individual; and Roberts also requires a transdermal treatment system (TTS) that is highly impractical for the average self-medicating individual. For example, Roberts requires the use of patches, plastic, disc, sachet, sheet, laminated reservoir etc. see column 1 lines36-51 and column 8 lines 24-34 In contrast, the present invention requires none of these accessories and is effectuated merely by applying a drop of an eye drop solution or a half second spray of a nasal spray and then smearing hydrocortisone, a compound readily available in the pharmacy.

Roberts is also impractical to apply to the problem the present invention solves because it is too risky. At best (if it even works for the therapeutic agent of the present invention), small changes in the concentration of the

phenylephrine relative to the concentration of the antihistamine and corticosteroid and relative to the depth of penetration may make the difference between increasing absorption of the therapeutic agent, maintaining its level or even decreasing it. It is not known if a concentration of phenylephrine HCL could ever be nailed down.

Besides all of the above, the maximum that Roberts can be said to teach about affecting any therapeutic agent at any depth of penetration and relative to any concentration of therapeutic agent, is possible increases in absorbability, concentration and/or local perfusion. Roberts teaches nothing about effectiveness, and particularly about dramatically increasing the effectiveness of combinations of antihistamines and corticosteroids. The present invention, in contrast, is a synergism of three ingredients that dramatically and speedily brings relief of dermatological symptoms using known formulations that are easily applied. One cannot merely assume that absorption translates into effectiveness.

The examiner responded to Applicant's reference to an internal contradiction in Roberts suggesting that it is not likely that the invention of Roberts really works with both vasoconstrictors and vasodilators" (see Roberts column 6 lines 15-24 versus column 6 lines 25-31) by contending that this is irrelevant since Roberts' teachings need only be true concerning vasoconstrictors or vasodilators, not both. The examiner neglects the fact that this apparent contradiction calls into question the credibility of Roberts with respect to *any* kind of vaso-active agent since a contradiction like this undermines Roberts' overall

credibility. The internal contradiction of Roberts may be explained in part by the fact that the teachings of Roberts are vague and depend so much on future experimentation with particular therapeutic agents, particular vaso-active agents and particular depths of concentrations useful in particular medical conditions, all left unspecified by Roberts.

New claims 43-44 are supported by the Specification. For example, most of the examples (pages 14-19) involve eye drops solution.. In addition, page 12 lines 19-21 and page 15 lines 1-3 support the period of "approximately one half second" used in claim 44. In other respects the claims 43-44 resemble independent claims 1 and 27.

It is respectfully requested that claims 1-6, 12-20, 26-29, 32-35 and 41-44 are not taught by the combination of the prior art cited and are in condition for allowance. It is hereby requested that the above amendment be entered and that these claims be allowed.

A payment of $677 including $405 for a RCE and $272 for the new claims, accompanies this Amendment in the form of a check drawn on an attorney escrow account.

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